

Effect of Posterior Tibial Nerve Stimulation and Trospium Hydrochloride in Treatment of Overactive Bladder Syndrome: A Randomized Controlled study

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ABSTRACT

Objective: To compare the effects of long term posterior tibial nerve electrical stimulation and trospium hydrochloride on urodynamic parameters, bladder diary and severity of urgency in patients with overactive bladder syndrome. **Design:** Randomized controlled trial. **Subjects:** Thirty-seven patients were divided into either posterior tibial nerve electrical stimulation (Group (1)-19 patients) or trospium hydrochloride (Group (2)- 18 patients). **Main outcome measures:** All patients were assessed at the beginning of the treatment, at week 12 (end of treatment), 18 and 24 according to urodynamic parameters, voiding diary parameters and severity of urgency (visual analogue scale, VAS). **Results:** Statistically significant improvements were observed in both groups according to some urodynamic parameters, voiding diary parameters, VAS urgency severity at the end of the treatment. During the 24-week follow-up period, deteriorations were observed in many parameters in both groups although improvements in the volume at first desire to void, frequency of urgency and VAS urgency severity in group 1 persisted. Significant differences were not detected between groups at the end of the treatment or during the post treatment follow-up controls. **Conclusion:** No difference was detected in long term of posterior tibial nerve electrical stimulation and trospium hydrochloride in the treatment of patients with overactive bladder syndrome. Discontinuation of both treatments caused deterioration in most of the symptoms of overactive bladder syndrome.

Key Words: Posterior Tibial Nerve Stimulation, Trospium Hydrochloride, Overactive Bladder.

INTRODUCTION

Overactive bladder syndrome is defined as urgency, with or without urgency incontinence, usually with frequency and nocturia¹.

Overactive bladder syndrome affects individuals adversely, both physically and psychosocially, and worsens their quality of life. It also causes infection, sleep disorders and depression and places a significant burden on health economics².

Non-neurogenic lower urinary tract dysfunction is a common urological problem that strongly affects quality of life. Patients can complain of urgency and frequency, urge incontinence, chronic pelvic pain or present with urinary retention. In most patients the etiology of these complaints remains unclear³.

Overactive bladder syndrome is a common disorder, which can have a significant negative impact on quality of life, impairing several areas, including emotional well-being, productivity at home and at work, social relationships, sexual intimacy and physical functioning⁴.

Pharmacological treatment comprises the main therapeutic modality in overactive bladder syndrome. However, the adverse effects of antimuscarinic therapy can influence a patient's quality of life and result in suboptimal dosing, poor patient compliance and even drug discontinuation. Trospium chloride, which was approved for overactive bladder syndrome recently and is gaining popularity, improves urodynamic parameters and symptoms markedly with fewer side-effects (anticholinergic and central nervous system side-effects) than other anticholinergics⁵.

The most commonly used non-drug treatment modalities include bladder training, pelvic floor muscle training and electrical stimulation. Electrical stimulation has been suggested to permit an effective inhibition of detrusor activity and reported as safe and effective for urinary incontinence⁶.

Posterior tibial nerve stimulation is a minimally invasive neuromodulation system

designed to deliver retrograde electrical stimulation to the sacral nerve plexus through percutaneous electrical stimulation of the posterior tibial nerve⁷.

So the present study was carried out to compare long term posterior tibial nerve electrical stimulation and trospium hydrochloride on urodynamic parameters, bladder diary and VAS urgency severity in patients with overactive bladder syndrome.

MATERIAL AND METHODS

Subjects

The study was conducted on 37 patients (male and female) who presented to Almatarya National Institute of Urology with urge incontinence and had overactive bladder or mixed type urinary incontinence with predominantly overactive bladder symptoms. Exclusion criteria were history of pelvic surgery, post-voiding residual volume 4100 mL, neurological deficit or peripheral neuropathy that may cause neurogenic bladder, presence of a medical condition that may preclude anticholinergic drug use, pregnancy or suspicion of pregnancy, cardiac pacemaker, genitourinary infection or haemorrhage, and deterioration in cognitive or intellectual functions. None of the patients were on anticholinergics or tricyclic antidepressants, and none had been treated by pelvic floor exercise, bladder training or pelvic surgery before entry into the study. All subjects gave written informed consent to participate in the study.

Fifty patients were selected initially for this study. Eight patients did not fulfil the criteria and were therefore excluded from the study. Five patients refuse to participate in the study. The patients who consented to participate were initially assessed by the third author. Then the researcher randomized each patient into one of the two groups by opening sealed envelopes. The randomization list was generated by a blinded researcher (The second author) using a table of random numbers. The randomization results were kept in sealed envelopes, one for each patient. There was no complete blindness in the study, since stimulation was applied by a separate

researcher, while examination and data collection were carried out by a different researcher.

Thirty-seven patients were randomized to the posterior tibial nerve electrical stimulation group (Group 1, n=19) and medical treatment (trospium hydrochloride) group (Group 2, n=18) by sealed envelope. Three patients in group 1 and one patient in group 2 could not complete the study. Sixteen patients in group 1 and seventeen patients in group 2 completed the study (Figure 1).

Detailed histories related to incontinence (type of incontinence and duration of incontinence) of patients before treatment and patient demographics (age, gender and body mass index) were gathered by face-to-face interviews. Urological and neurological examinations, urinalysis and urine culture were performed. The patients in group 1 did not take placebo tablets, and the patients in group 2 did not have sham PTNS. Accordingly, the treatment was planned to cover twelve weeks period. All patients were evaluated using the following methods at baseline, week 12 (end-of-treatment), 18 and 24.

Urodynamic examination

Urodynamic examination was performed with the Dantec Duet system (Dantec, Denmark). Urodynamic examination was performed after appropriate antimicrobial treatment when infection was diagnosed by urine culture. A double-lumen cystometry catheter was used to fill the bladder with 0.9% saline solution at a rate of 20 mL/min. Volume at first desire to void and maximal detrusor pressure during filling phase.

Voiding diary

Before each assessment, patients were asked to fill in a three-day voiding diary that included daily voiding frequency (n/day) and frequency of urgency before voiding (n/day).

Visual analogue scale (VAS)

In addition to voiding diary parameters, patients were asked to show the severity of urgency. A 10-cm visual analogue scale (VAS) was used to assess the severity of

urgency in the patients. The VAS used a 10-cm line oriented vertically with 'no urgency' corresponding to the bottom of the line and 'worst imaginable urgency' to the top of the line. Patients were instructed to place a mark on the 10-cm vertical line that corresponded to their severity of urgency. Moreover, before treatment, all patients were given an instructional leaflet showing behavioral modifications to get incontinence and urgency attacks under control.

Treatment procedure

Patients in group 1 underwent posterior tibial nerve electrical stimulation for twelve weeks, three times a week, for 30 minutes each. PTNS was applied unilaterally with 26-gauge stainless steel needles (disposable concentric needle Medtronic, Minneapolis, Minn) inserted 5-cm cephalad from the medial malleolus and posterior to the edge of the tibia, placing the ground electrode on the ipsilateral extremity. Electrical stimulation (Medtronic

Key Point Net, Medtronic) was applied unilaterally by using charge-compensated 200 microsecond pulses with a pulse rate of 20 Hz. Intensity level was then chosen as the intensity immediately under the threshold determining motor contraction. Before the start of urodynamic recording electrical stimulation was triggered with a push button to determine the appropriate stimulation amplitude and to confirm correct needle placement. The stimulation amplitude was set at the maximum tolerable level according to the subject under investigation, which was usually 1.5 times the threshold for evoking plantar flexion of the toes and/or toe fanning (range: 1 to 5 mA).

Patients in group 2 were given trospium hydrochloride (Spasmex 30-mg tablet) for twelve weeks at a dose of 45 mg/day, 30 mg in the mornings and 15 mg in the evenings. Compliance was calculated at weeks 12, 18 and 24 by subtracting the number of medication capsules returned by each subject from the number originally dispensed.

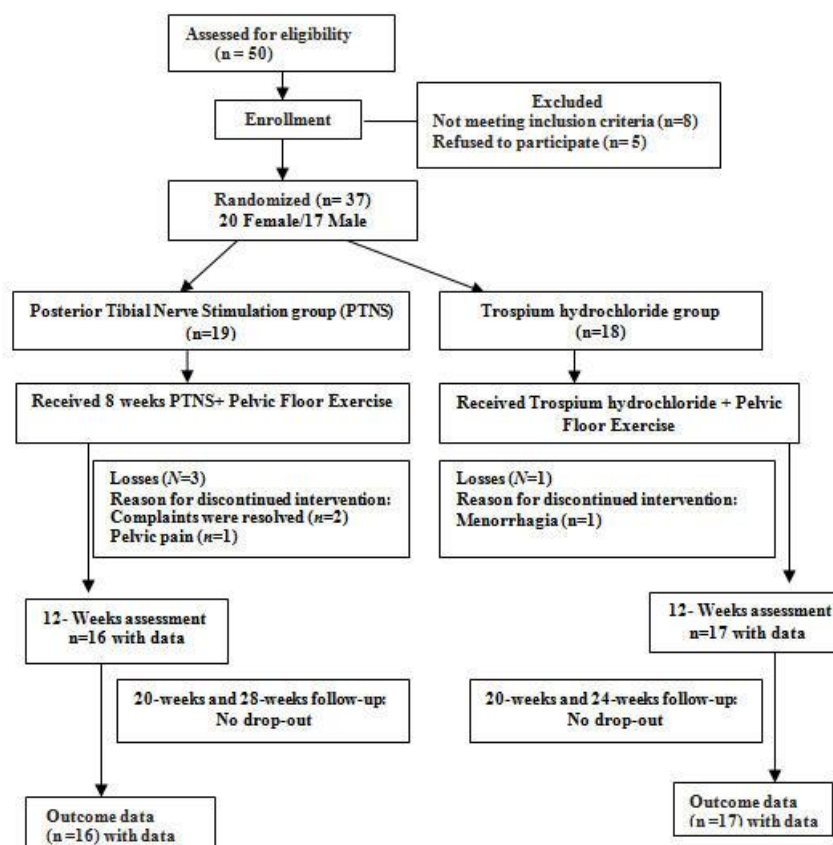


Fig. (1): Flow diagram of the study.

Statistical analysis

Data were analyzed using SPSS for Windows version 10.0 statistical package

(SPSS Inc., Chicago, IL, USA). Mann-Whitney U-test was used to compare the urodynamic parameters, voiding diary and

VAS measurements between groups. Comparisons between pre- and post-treatment within groups were tested by the Wilcoxon test; a level of 0.05 was accepted as significant.

RESULT

Prior to the training period, there is no statistically significant differences were found in the demographic characteristics when the two groups were compared for any variables as in Table (1). Similarly, both groups were comparable with respect to urodynamic parameters (volume at first desire to void, maximal detrusor pressure during filling phase), voiding diary parameters (daily voiding frequency (n/day) and the frequency of urgency before voiding (n/day), VAS (severity of urgency).

Results of Urodynamic Parameters

There are significant increases in volume at first desire to void at the end of the treatment (week 12) in both groups (Table 2). Even though there was a decrease in maximal detrusor pressure in both groups at the end of treatment (week 12), only that in group 1 was statistically significant (Table 2).

During the follow-up visits following treatment (week 12). In both groups, the volume at first desire to void tended to decrease at week 18, reaching a level at week 24 that was statistically significantly different from baseline ($P<0.05$, Table 2). Increase in maximal detrusor pressure was observed after treatment in both groups, but the difference between the baseline and week 24 was not significant ($P<0.05$). There were no significant differences between groups during all controls

after treatment in terms of urodynamic parameters ($P<0.05$).

Voiding diary

With regard to the voiding diary parameters, frequency of urgency voiding improved at the end of treatment (week 12) in both groups ($P<0.05$, Table 2). During the follow-up evaluations after treatment (week 12), the frequency of urgency in Group 1 increased from the end of treatment (week 12) until week 24 and the frequency of urgency at week 24 were significantly lower than the baseline ($P<0.05$, Table 2). In group 2, on the other frequency of urgency decreased at week 18 and frequency of urgency were lower at week 24 compared to the baseline ($P<0.05$, Table 2). Improvement in the voiding frequency continued at a significant level until week 18 in both groups, but at week 24, the difference compared to baseline was not significant ($P<0.05$, Table 2). Comparisons between groups after the treatment did not reveal any significant differences in terms of voiding diary parameters ($P<0.05$).

VAS urgency severity

VAS urgency severity decreased significantly in both groups after treatment (week 12) ($P<0.05$, Table 2). During the follow-up assessments, even though the VAS urgency severity gradually increased after treatment (week 12) until week 24 in group 1, the VAS urgency severity was still significantly lower than the baseline ($P<0.05$, Table 2). In group 2, on the other hand, the decrease persisted after the end of treatment (week 12) and was significantly lower than the baseline at week 18 ($P<0.05$, Table 2). Comparisons of the groups after treatment did not reveal any significant differences in terms of urgency severity ($P<0.05$).

Table (1): Subject Characteristics (Mean \pm SD) for both groups.

	Group 1 (Posterior tibial nerve stimulation + Pelvic floor exercise) (n=16)	Group 2 (Trosipium hydrochloride + Pelvic floor exercise) (n=17)
Age (year)	51.68 \pm 6.60	50.62 \pm 6.83
Body mass index, kg/m ²	30.07 \pm 6.27	31.41 \pm 5.42
Duration of incontinence (years)	4.25 \pm 1.91	4.82 \pm 1.94
Type of incontinence Urge/Mixed	11/5	13/4
Gender (Male/Female)	6/10	7/10

Table (2): Comparison of posterior tibial nerve electrical stimulation (Group 1) and tiroprium hydrochloride (Group 2) with respect to the urodynamic parameters, voiding diary, severity of urgency (VAS).

	Pre -T		Post -T (week 12)		Post-T (week 18)		Post-T (week 24)	
	Group1	Group2	Group1	Group2	Group1	Group2	Group1	Group2
Urodynamics Volume at first desire	126.5	120.0	205.0*	210.0*	205.5*	157.0* ^A	151.0*	149.5* ^{B,C}
Maximal detrusor pressure	27	29	23*	13	31.0 ^A	28	18	27
VAS (severity of urgency)	57.5	58.0	32.0*	24.5*	27.0*	31.5*	16.0*	36.5*
Voiding diary Frequency of urgency	4.5	5.5	1.8*	2.8*	1.4*	3.6*	3.0*	4.4* ^B
Voiding frequency	8.5	10.40	7.0*	6.0*	6.1*	8.0* ^A	6.5	8.3 ^B

Pre-T, before treatment; Post-T, after treatment; VAS, visual analogue scale.

*Pre-treatment comparison: P < 0.05.

^A Comparison of Post-T (week 18) and Post-T (week 12): P< 0.05.

^B Comparison of Post-T (week 24) and Post-T (week 12): P<0.05.

^C Comparison of Post-T (week 24) and Post-T (week 18): P<0.05.

DISCUSSION

This study conducted to examine the effect of posterior tibial nerve electrical stimulation and tiroprium hydrochloride on urodynamic parameters, voiding diary and severity of urgency in patients with overactive bladder syndrome. The results of this study revealed improvements in urodynamic parameters, voiding diary parameters and severity of urgency with treatment in both groups. Even though there were deteriorations in many of these parameters with the cessation of treatment, improvements in the volume at first desire to void, frequency of urgency and VAS urgency severity continued in the electrical stimulation group.

Application of various forms of electrical stimulation is considered as therapeutic option to manage different types of lower urinary tract dysfunction⁷. Detrusor muscle overactivity was suppressed by electrical stimulation without reducing its contractile force⁸, also there was increased beta adrenergic activity in the detrusor muscle after pelvic floor electrical stimulation, whereas cholinergic receptor activity was reduced⁹.

The main treatment goal of overactive bladder syndrome is to inhibit detrusor overactivity and thus to increase functional bladder capacity¹. Previous studies showed that in overactive bladder syndrome, tiroprium hydrochloride leads to improvement in urodynamic parameters compared to placebo^{10,11}. Few studies have explored the effects of electrical stimulation on urodynamic parameters, and these studies presented evidence that it causes improvements^{12,13}.

Posterior tibial nerve electrical stimulation was chosen as the physiotherapeutic method because it is an interesting alternative for the treatment of overactive bladder, which is effective and without side effects, despite the fact that pharmacological treatment is currently the first option for the treatment of patients with clinical symptoms of overactive bladder, adherence to treatment is low, especially due to side effects which lead to discontinuation in 60% of cases. Posterior tibial nerve electrical stimulation is considered to be a simpler, less invasive and easy to apply form of peripheral sacral stimulation that is well tolerated by patients and more affordable¹⁴.

Pelvic floor muscle exercises increase muscle volume and strength, so it is recommended as a treatment for men with urinary frequency, terminal dribbling, and urinary incontinence, pelvic floor exercises seem to help in reducing symptoms and provides better psychological and social quality¹⁵.

The psychological well-being of patients with overactive bladder syndrome is important for the quality of life; no studies have investigated the effects of anticholinergic and electrical stimulation treatments on the psychology of patients. Our result indicates that both anticholinergic treatment and electrical stimulation markedly improved the depressive symptoms. This was attributed to the decrease in symptoms and consequent psychological well-being. Moreover, this effect continued even after the termination of the electrical stimulation treatment.

The result is consistent with previous studies which stated that PTNS produce improvement in bladder instability, voiding frequency and bladder capacity by urodynamics evidence, also effect of PTNS on patients with over active bladder symptoms (urgency, frequency) had a good results and urodynamics parameters were improved after treatment and statistically significant decrease in leakage episodes, frequency and nocturea^{16,17,18}.

In this study, it was found that patients were satisfied with both treatments. This indicates that both treatments can be used in clinical practice. However, when side-effects are considered, electrical stimulation caused fewer side-effects than anticholinergic treatment. The side-effects observed with electrical stimulation and anticholinergic treatment is similar to those in the literature^{5,11}.

Voiding diary is an objective tool to assess urodynamic parameters in patients with overactive bladder. In this study, significant improvements were observed in the voiding diary and urgency severity in both treatment groups. Improvements in voiding habits as a result of treatment observed in the electrical stimulation^{12,19} and trosipium hydrochloride groups are in agreement with the literature²⁰. A study that investigated the effects of electrical

stimulation and anticholinergic treatment on the voiding diary argued that electrical stimulation was more effective than anticholinergic treatment²¹ Wang 2006, though studies have also shown that the two treatments were equally effective^{22,23,24}.

In the week 20 follow-up period, although there was no difference between the treatment groups in terms of the examined variables, it was observed declines in voiding parameters and urgency severity following the termination of treatment in the trosipium ydrochloride group whereas improvements in voiding parameters and urgency severity continued in the electrical stimulation group. Because of this favourable effect of electrical stimulation, we are of the opinion that studies with longer follow-up periods are needed.

Finally, both posterior tibial nerve stimulation and trosipium hydrochloride were similarly effective in patients with overactive bladder syndrome, and thus the continuation of these two treatments is important because the discontinuation of these treatments would cause a relapse of most of the symptoms of overactive bladder syndrome. However, further studies are needed to compare the effects as well as the treatments' superiority over one another in long-term use.

Conclusion

Posterior tibial nerve stimulation and trosipium hydrochloride have an equivalent effect in the treatment of patients with overactive bladder syndrome and discontinuation of both treatments causes deterioration in most of the objective and subjective symptoms of overactive bladder syndrome and the two line of treatment can be used safely in clinical applications.

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المخلص العربي

دراسة تأثير التنبيه الكهربائي للعصب الظنبوبي الخلفي وعقار تروسبيام هيدروكلوريد في علاج متلازمة فرط نشاط المثانة : دراسة محكمة عشوائية

تهدف الدراسة لمقارنة تأثير التنبيه الكهربائي للعصب الظنبوبي الخلفي وعقار تروسبيام هيدروكلوريد على قياسات اليوروديناميك للمثانة ، مذكرات المثانة وشدة الإلحاح في المرضى الذين يعانون من متلازمة فرط نشاط المثانة . تم تقسيم سبعة وثلاثون مريضاً إما إلى التنبيه الكهربائي للعصب الظنبوبي الخلفي (المجموعة الأولى) أو عقار تروسبيام هيدروكلوريد (المجموعة الثانية) . تم تقييم جميع المرضى في بداية العلاج ، في نهاية الأسبوع الثاني عشر (نهاية العلاج) ونهاية الأسبوع الثامن عشر ونهاية الأسبوع الرابع والعشرون وفقاً لقياسات اليوروديناميك ، مذكرات المثانة وشدة الإلحاح . **النتائج :** لوحظ وجود تحسن ذو دلالة إحصائية في كلا من مجموعتي الدراسة وفقاً لبعض قياسات اليوروديناميك ، مذكرات المثانة وشدة الإلحاح في المرضى في نهاية فترة العلاج ، لكن خلال فترة المتابعة في نهاية الأسبوع الرابع والعشرون ، لوحظ وجود تدهور في العديد من القياسات في كلا من المجموعتين على الرغم من وجود تحسن ذو دلالة إحصائية في المجموعة الأولى طرأت على بعض قياسات جهاز اليوروديناميك للمثانة وشدة الإلحاح . وتم تلخيص النتائج عن عدم وجود اختلافات كبيرة بين المجموعتين في نهاية العلاج أو بعد العلاج خلال متابعة القياسات . **الخلاصة :** تم الكشف عن عدم وجود فرق بين التنبيه الكهربائي للعصب الظنبوبي الخلفي وعقار تروسبيام هيدروكلوريد على المدى الطويل في علاج المرضى الذين يعانون من متلازمة فرط نشاط المثانة . **الكلمات الدالة :** التنبيه الكهربائي للعصب الظنبوبي الخلفي ، عقار تروسبيام هيدروكلوريد ، فرط نشاط المثانة .